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10/678,593

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EXAMINER

ALTER, ALYSSA MARGO

ART UNIT

PAPER NUMBER

3762

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |                                       |  |
|------------------------------|--------------------------------------|---------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/678,593 | <b>Applicant(s)</b><br>VAISNYS ET AL. |  |
|                              | <b>Examiner</b><br>Alyssa M. Alter   | <b>Art Unit</b><br>3762               |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 January 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,5 and 7-48 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,5 and 7-48 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                     |                                                                   |
|-------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____                                                         | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Response to Arguments***

Applicant's arguments see page 12, filed January 13, 2010 have been fully considered but they are not persuasive.

The Applicant argues that the LEDs of Fincke et al. do not function as the status indicator since they do not describe or disclose the operational status of the portable AED. However, since the battery is part of the defibrillation circuitry (as disclosed by Applicant in claim 8), determining the status of the battery would thus determine the operational status of the defibrillation circuitry. Furthermore, the examiner considers the determination of the operational status to equate to a performance of a self test.

Additionally the Applicant argues that the claims would not be rendered obvious under Olson et al. in view of Fincke et al. The Applicant has argued that if the indicator of Olson et al. was replaced with a light, such as the LEDs in Fincke et al., it would "at best blink once" since it would "require Olson's AED to provide continuous power". However, this is arguing a limitation not set forth in the claims (i.e. the continuous power draw of the light source). In addition, even one blink of a light source would "illuminate the light source....continually during an interval".

Therefore, the claims remain rejected under Olson et al. in view of Fincke et al.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

Art Unit: 3762

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 1-2, 4-5, 7-48 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification does not provide support for "a computer" or "a computer running programming" in combination with the other elements in the claims. Furthermore, the specification does not provide support for an "ultimate self-test" in combination with the other elements in the claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 9, 15 and 41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 9, 15 and 41 recites the limitation "electrode pads" in line 2. There is insufficient antecedent basis for this limitation in the claim and the "electrode pads" are inferentially included.

2. Claims 1, 4-5 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. As to claims 1 and 8, it is unclear if there is an element set forth to determine if the circuitry is "OFF".

Furthermore, no means or structures are set forth in claim 1 to determine “normal” operation of the external defibrillator.

In addition, claims 1 and 8 state that “the defibrillation circuitry including a computer running [operating] programming...a switch....an active status indicator”. The claim later recites that the light source illuminates due to computer programming when the circuitry is OFF. However, this seems inconsistent since the computer is part of the defibrillation circuitry. Thus if the circuitry is OFF, so would the computer running the programming. Therefore, it is unclear how the computer programming can run if it is OFF along with the rest of the defibrillation circuitry.

Similarly, claim 8 recites the defibrillation circuitry including a battery pack removable connected to the defibrillation circuitry. This appears to be inconsistent since the defibrillation circuitry *requires* a battery. It appears to read that the battery pack is connected to itself.

As to claims 4 and 5, no means or structures are set forth during the “ultimate self test” to determine “that maintenance is required” for the external defibrillator.

Additionally, as to claim 8, it is unclear how the “light source” is “operated autonomously” by the programming, since autonomously would be free from outside control (i.e., the programming).

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Art Unit: 3762

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 1-2, 4-5, 8 and 36-40 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Fincke et al. (US 5,470,343). Fincke et al. discloses an external automated defibrillator (AED) with a removable battery pack connected to the circuitry. Since the battery is part of the defibrillation, and since it provides power to the defibrillation circuitry, the examiner considers the battery to be part of the defibrillation circuitry.

Fincke et al. further discloses a removable power supply having five indicator LEDs 52a-52e, collectively referred to as indicator LEDs 52 in figure 1. The examiner considers the LEDs 52, particularly LED 52e to be the active status indicator that comprises a light source. The LED 52e illuminates flashing yellow when the power supply needs to be connected to a source of AC power which occurs when the power supply is attached to the defibrillator and not to an AC power source, the battery is in place and the defibrillator is turned off (i.e. in standby). Therefore, since the defibrillator is turned off, the AED is thus in a standby mode. Furthermore the examiner considers the indicator to illuminate when the AED is in standby mode ready to operate.

Fincke et al. discloses in col. 8, lines 25-28, that the "measurement circuits 80 monitor the output voltage of output circuit 66, the current supplied to battery 54, and

Art Unit: 3762

other signals, to provide information that allows microprocessor 76 to determine the charge status of battery 54". Thus, examiner considers the microprocessor to be a computer that monitors the defibrillation circuitry. In addition, since the battery status is determined, the examiner considers this to be a self test that determines the operational status of the circuitry.

Furthermore, Fincke et al. discloses the microprocessor monitors the on/off state of the defibrillator, in col. 8, lines 46-51. Therefore Fincke et al. necessarily includes an on/off switch to shift between on and off state or operational to standby mode.

In the alternative, although the examiner considers Fincke et al. to discloses a switch, it would have been obvious to one having ordinary skill in the art at the time the invention was made to include an on/off switch in order to provide the predictable results of turning the defibrillator on and off in order to conserve power/battery consumption. Furthermore, on/off switches are extremely well known in the art.

As to claims 2 and 37, the defibrillator circuitry causes a different illumination of the active status indicator LEDs 52, particularly 52c, when the circuit is operating normally in the operational mode. The green illumination of 52c differs from the flashing yellow of 52e.

As to claims 4 and 38, the defibrillator circuitry causes a different illumination of the active status indicator LEDs 52, particularly 52d, when the AED detects a fault in the power supply or battery. Therefore the examiner considers the LED 52d to illuminate when maintenance is required and the AED is in operational mode.

As to claims 5 and 39, the defibrillator circuitry causes a different illumination of the active status indicator LEDs 52, particularly 52b, when the AED detects the battery is present and receiving a charge. The examiner considers the 'charging' status to be maintenance is required by the defibrillator (i.e. the need to charge the battery).

2. Claim 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fincke et al. (US 5,470,343) or the modified Fincke et al. as applied to claims 1-2, 4-5, 8, 13, 36-40 and 42 above. Fincke et al. discloses the device substantially as claimed except for two processors. It would have been obvious to one having ordinary skill in the art at the time the invention was made to include two processors instead of one processor since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8 (see MPEP 2144.04). Furthermore, such a modification would provide the predictable results of designating different tasks to each processor. Additionally, two processors with different functions would enhance troubleshooting and replacement in the event an error is detected with the AED.

3. Claims 1-2, 8-10, 12-16, 19-22, 25-30, 33-38 and 40-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Olson et al. (US 5,645,571) or in the alternative, Olson et al. (US 5,645,571) in view of Fincke et al. (US 5,470,343). Olson et al. discloses an automated external defibrillator (AED) having a switch, rescue switch 18, for switching the AED from a standby mode to an operational mode and a visual maintenance indicator 20 which the examiner considers to be an active status indicator. Furthermore, during the open-lid self test, the maintenance indicator is switched to a

Art Unit: 3762

yellow color indicating a maintenance required state. This mode, the self test, precedes the rescue mode and is thus considered to be standby mode.

Olson et al. discloses an active status indicator, but does not expressly teach the employment of a light source (such as an LED or light bulb) as the active status indicator. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the active status indicator to include a light source to illuminate the indicator in order to provide the predictable results of enhancing the maintenance notification system within the AED.

In the alternative, Olson et al. discloses an active status indicator, but does not expressly teach the employment of a light source. Fincke et al. discloses a removable power supply having five indicator LEDs 52a-52e, collectively referred to as indicator LEDs 52 in figure 1. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the active status indicator of Olson et al. with an LED or light source as taught by Fincke et al. in order to provide the predictable results of notifying the operator of required maintenance or the status of the AED.

As to claim 2, when the defibrillator is in operation mode, the maintenance indicator changes to a black color, which is different from the first illumination.

As to claim 8, Olson additionally discloses a removable battery pack.

As to claim 9, 12-15 and 19-21, "If the monitored impedance is out of range (e.g., too high if the electrodes have come off the patient, or too low if shorted), processor 74 initiates the generation of a "Check Electrodes." voice prompt"(col. 6, lines 56-60).

Art Unit: 3762

As to claims 10, 16, 22, 30, 42, 44, 46 and 48, the modified Olson et al. discloses employing LEDs as indicators. Fincke et al. discloses it is known to employ blinking LEDs or different types of illuminations. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the LED indicators as taught by the modified Olson et al. with blinking LEDs as taught by Fincke et al. since they would provide the predictable results of drawing attention to the medical device's operational state. For example, blinking LEDs can be employed when a machine is in the process of dispensing therapy or recharging.

4. Claims 4-5, 7, 11, 17-18, 23-24, 31-32 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over the modified Olson et al. as applied to claims 1-2, 8-10, 12-16, 19-22, 25-30, 33-38 and 40-48 above.

As to claim 7, the modified Olson et al. discloses the claimed invention except for second processor. It would have been obvious to one having ordinary skill in the art at the time the invention was made to include a second processor, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8 (see MPEP 2144.04).

Furthermore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the one processor with two processors since it was known in the art that two processor provide the predictable results of decreasing processing time as well as function as a back-up to the first processor.

As to claims 4-5 and 39, Olson et al. discloses the claimed invention except for third and/or fourth illumination. It would have been obvious to one having ordinary skill

Art Unit: 3762

in the art at the time the invention was made to use an indicator with multiple illuminations in order to provide the predictable result of reducing the components employed by the AED. If there was only one indicator and it provided multiple illuminations, either through different colors or different patterns (i.e. blinking or pulsing), then only one indication could be used to indicate several different states, functions or errors with the AED. Thus reducing manufacturing and maintenance costs by eliminating the need for an employing an entire panel of indicators.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Art Unit: 3762

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alyssa M. Alter whose telephone number is (571)272-4939. The examiner can normally be reached on M-F 8am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno can be reached on (571) 272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/George R Evanisko/  
Primary Examiner, Art Unit 3762

/Alyssa M Alter/  
Examiner  
Art Unit 3762